

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* RICHARD J. LAZZARA, THOMAS S. HEYLMUN, and  
KEITH D. BEATY

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Appeal 2007-0192  
Application 09/237,605  
Technology Center 3700

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Decided: November 13, 2007

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Before MURRIEL E. CRAWFORD, JENNIFER D. BAHR, and  
LINDA E. HORNER, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

STATEMENT OF THE CASE

Richard J. Lazzara et al. (“Appellants”) have filed a request for rehearing under 37 C.F.R. § 41.52 seeking reconsideration of our decision of May 30, 2007 (“Decision”), wherein we reversed the rejection of claims 51 and 60-75 under 35 U.S.C. § 103(a) and entered a new ground of rejection of claims 51 and 60-75

under 35 U.S.C. § 112, second paragraph. The Appellants argue that the Board misapprehended or overlooked that “the claim language in question – ‘substantially uniform array of irregularities’ – is acceptable according to [the] Federal Circuit” (Request for Rehearing 2). As such, the Appellants request the Board to reconsider its decision to enter a new ground of rejection under 35 U.S.C. § 112, second paragraph, and request the Board to review the rejection of the pending claims under 35 U.S.C. § 103.

#### ANALYSIS

In our Decision of May 30, 1997, we found that the claimed “substantially uniform array of irregularities” was ambiguous and that neither the remainder of the claim language, nor the Specification, nor the Declarations submitted in the Evidence Appendix attached to Appellants’ Brief, provided any description of a standard for measuring the degree of uniformity such that one of ordinary skill in the art would understand what is meant by “a substantially uniform array of irregularities” as claimed (Decision 12-13).

The Appellants request that we reconsider our decision in light of Federal Circuit cases which found, within the context of claim interpretation post-grant in an infringement dispute, that the term “substantially” and the phrase “substantially uniform” are amenable to interpretation using their ordinary and customary meanings (Request for Rehearing 2-4). The Appellants appear to be arguing that the cited Federal Circuit case law stands for a *per se* rule that if the term “substantially” is used in a claim, and if the Specification fails to provide a

definition of the term with numerical specificity, then the term must be interpreted broadly in accordance with its customary meaning. We do not read the Federal Circuit cases to stand for such a *per se* rule.

Rather, the case law requires some sort of standard by which one of ordinary skill in the art can measure a term of degree such as “substantially” so as to understand what is claimed. While the standard for measuring a term of degree need not be defined with numerical specificity, the standard must be able to be derived from information in the patent regarding the purpose of the invention – or of the specific aspect of the invention to which the term of degree applies – as well as from experimentation. *See Seattle Box Co. v. Indust. Crating & Packing, Inc.*, 731 F.2d 818, 820-21, 826 (Fed. Cir. 1984).

The Appellants rely, in particular, on the cases of *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352 (Fed. Cir. 2003) and *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358 (Fed. Cir. 2001), in which the court interpreted claim elements including the phrase “substantially uniform” (*Id.*). In *Cordis*, the court interpreted the meaning of a claimed stent composed of a tubular member having a “wall surface having a substantially uniform thickness.” The court in *Cordis* noted that “[t]he patents [at issue] do not set out any numerical standard by which to determine whether the thickness of the wall surface is ‘substantially uniform.’” *Id.* at 1360. The court found that “[t]he term ‘substantially,’ as used in this context, denotes approximation.” *Id.* (citation omitted). As such, the court held that “the walls must be of largely or approximately uniform thickness.” *Id.* The Specification likewise did not provide any further definition of the variation for

which the thickness of the wall surface would be “substantially uniform.” *Id.* The court held that because there was no clear and unmistakable surrender of claim scope during the prosecution history of the patent, the broad definition of “substantially uniform thickness,” i.e., that “the walls must be of largely or approximately uniform thickness,” was the proper definition. *Id.* at 1362.

In *Ecolab*, the court stated that “nonnumerically limited descriptive claim terms are construed using the same rules of construction as any other claim term.” 264 F.3d at 1366. The court in *Ecolab* thus construed the claim element “substantially uniform alkaline detergent” by reviewing the intrinsic evidence, which consists of the claim language, the written description, and the prosecution history. *Id.* (citation omitted). The court explained,

This intrinsic evidence is consulted to determine if the patentee has chosen to be his or her own lexicographer, or when the language itself lacks sufficient clarity such that there is no means by which the scope of the claim may be ascertained from the claim language itself. (internal citations omitted). When the foregoing circumstances are not present, we presume that the terms in the claim mean what they say. In other words, we follow the general rule that terms in the claim are to be given their ordinary and accustomed meaning.

*Id.* (citations omitted) (emphasis added). The court provided the ordinary and customary meanings of the terms “substantially” and “uniform,”<sup>1</sup> found that the

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<sup>1</sup> The court looked to the dictionary definitions of “substantially,” meaning “considerable in extent” or “largely but not wholly that which is specified” and “uniform,” meaning “always the same in degree; unvarying.” *Ecolab*, 264 F.3d at 1367 (citing, respectively, THE AMERICAN HERITAGE COLLECTION DICTIONARY 1475 (3d ed. 1997), AMERICAN HERITAGE DICTIONARY SECOND COLLEGE ED. 1213 (2d ed. 1982),

written description did not reveal any special definition for the terms, and further found that “the use of the term ‘substantially’ to modify the term ‘uniform’ does not render this phrase so unclear such that there is no means by which to ascertain the claim scope.” *Id.* at 1367. The court also found that the term “substantially” “is a descriptive term commonly used in patent claims to ‘avoid a strict numerical boundary to the specified parameter.’” *Id.* (quoting *Pall Corp. v. Micron Seps.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) (additional citations omitted)).

In light of these decisions, the Appellants submit that the proper definition of “substantially uniform array of irregularities,” based on the ordinary and customary meanings of the terms, is that “the irregularities described [in claims 51, 63, and 68] have largely, but not wholly, the same form, manner, or degree” (Request for Rehearing 4). The Appellants contend that this definition is consistent with the Specification, which describes the surface of Example 3 as having “a high level of etch uniformity over the surface,” meaning that “the irregularities on the roughened surface were not absolutely or perfectly uniform” (Request for Rehearing 4-5). As such, the Appellants argue that “the claims are as precise as the subject matter permits” (Request for Rehearing 5).

In a more recent Federal Circuit decision, however, the court in *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313 (Fed. Cir. 2005), declined to adopt the definition of “substantially uniform” from *Ecolab*, explaining:

A particular term used in one patent need not have the same meaning when used in an entirely separate patent,

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and WEBSTER’S NINTH NEW COLLEGIATE DICTIONARY 1176 (9th ed. 1983)).

particularly one involving different technology. In fact, there are many situations in which the interpretations will necessarily diverge. A patentee may define a particular term in a particular way, and in that event the term will be defined in that fashion for purposes of that particular patent, no matter what its meaning in other contexts. *See Hormone Research Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1563 (Fed. Cir. 1990). Moreover, claim terms are typically given their ordinary and accustomed meaning as understood by one of ordinary skill in the pertinent art, and the generally understood meaning of particular terms may vary from art to art. *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1332 (Fed.Cir.2001); *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1372 (Fed.Cir.2001). Even absent an express definition of a term in the specification or prosecution history, or a clearly established understanding of the meaning of the term in the art, the manner in which the term is used in the patent may dictate a definition that differs from the definition that would be given to the same term in a different patent with a different specification or prosecution history. *See Young Dental Mfg. Co. v. Q3 Special Prods., Inc.*, 112 F.3d 1137, 1143 (Fed.Cir.1997) (“The specification that is relevant to claim construction is the specification of the patent in which the claims reside.”).

*Id.* at 1318-19 (finding that “[t]he use of a term in a patent on a detergent [as in *Ecolab*] is of little pertinence to the use of a similar term in a patent on MRI RF coils. Rather, absent some particular reason to do otherwise, the claim terms must be interpreted as would one of ordinary skill in the art of MRI technology and in light of the particular patent in suit.”).

The court in *Medrad* first looked to the words of the claim itself in an attempt to define the metes and bounds of the “substantially uniform” recitation and found that “[t]he term ‘substantially uniform first magnetic field’ is ambiguous in that it fails to suggest how much a magnetic field may deviate from absolute uniformity before it is no longer uniform.” *Id.* at 1319. The Court found guidance for the definition of “substantially uniform” in the preamble, which claimed an “imaging system for forming images of a region of interest.” *Id.* at 1320. The court held that “[t]he problem of image distortion puts an upper bound on the degree of nonuniformity allowable in the magnetic field, which is part of an ‘imaging system for forming images of a region of interest.’” *Id.* The Court found that the interpretation was further supported by the Specification, which stated as an object of the invention to provide greater image uniformity than provided in the prior art, and found that the interpretation aligns with the conventional understanding of the term in the MRI industry, based on expert testimony of the meaning of “a substantially uniform magnetic field” in the art. *Id.*

As in *Medrad*, we find that the phrase “substantially uniform array of irregularities” used in the claims is ambiguous in that it fails to suggest how much the irregularities may deviate from absolute uniformity before they are no longer uniform. *See Medrad*, 401 F.3d at 1319. However, unlike in *Medrad*, we find no guidance in the remainder of the claims that would lead to an understanding of this claim limitation. While the claims require a roughened region (claim 51) or an acid-etched surface (claims 63 and 68) “for facilitating osseointegration with said bone,” there is no evidence in the record that the stated purpose of facilitating

osseointegration places an upper bound on the degree of nonuniformity allowable in the roughened region or acid-etched surface of the claims. On the contrary, the Specification indicates that it is the fact that the surface is roughened, and not necessarily the degree of uniformity of the irregularities, that promotes osseointegration with the bone (Specification 1: 13-14 and 17-18).

The claims also recite the steps of the acid-etching process, which include removing a native oxide layer and then uniformly acid etching with a second acid solution. This general description of the treatment method is insufficient to define what is meant by “substantially uniform array of irregularities” because, if it was, then Haruyuki would inherently contain such an array as it follows the same two-step treatment process. The Appellants have chosen to make “substantially uniform array of irregularities” the critical and defining limitation of the claim. As such, it must be clear as to what falls within its scope.

The parent application (now U.S. Patent No. 5,876,453), which is incorporated by reference in the present application (see Specification 3:23-25), describes the roughening or acid-etching process and further describes that it is a primary object to “produce an implant surface having a roughness that is substantially uniform over the area of the implant that is intended to bond to the bone in which the implant is placed” and a further object to “provide an improved surgically implantable device having on its surface a substantially uniform micromorphology (‘453 patent, col. 2, ll. 58-64). The parent application further describes that it is a more specific object of the invention to “provide an improved etch-solution process that will result in a substantially uniform surface topography

on surgically implantable devices" ('453 patent, col. 3, ll. 4-7). The parent application teaches that the fine roughness of the treated surface, in combination with the high degree of uniformity of that roughness over the treated surface, renders a surface topography that is "well suited for osseointegration with adjacent bone" ('453 patent, col. 6, ll. 27-31). While the uniformity of the array of irregularities is "well suited" for osseointegration, it is not clear from the Specification that a surface having arrays of irregularities that are not substantially uniform does not also facilitate osseointegration with the bone due to the roughness of the surface. As such, we fail to see how one having ordinary skill in the art would be able to decipher from the stated purpose of the invention what variation in uniformity is permitted in order to achieve the purpose of osseointegration.

The Appellants contend that "[a]n array of irregularities having a portion with irregularities having peak-to-valley heights of 1 to 3 microns and another portion with irregularities having peak-to-valley heights of 0.01 microns would not fall within the scope of the claims" because the "very purpose of including the term '**substantially uniform**' is to exclude surfaces in which the irregularities have 'widely varying heights'" (Request for Rehearing 6) (emphasis in original). We understand this argument to say that a variation in height of 0.99 microns between one portion of the array (having a height of 1 micron) and another portion of the array (having a height of 0.01 microns) would be considered not substantially uniform. We fail to see how this is the case in view of the Appellants' own Specification, which describes that its second etching process

results in a final etched surface consisting of a substantially uniform array of irregularities where “[s]ubstantial numbers of the irregularities … hav[e] base-to-peak heights in the range from about 0.3 microns to about 1.5 microns” (‘453 patent, col. 6, ll. 31-36). As such, the Appellants’ own working examples result in a variance of 1.2 microns between peaks. *See also* ‘453 patent, col. 8, l. 19 (Example No. 3 having arrays of cones ranging in height from about 0.3 microns to 2.0 microns for a variance of 1.7 microns).

Further, unlike in *Medrad*, we find no guidance in the declaration submitted by Dr. Gubbi on June 30, 2003 (“the Gubbi Declaration”), that would inform us as to how one of ordinary skill in the art of dental implants would understand the claimed “substantially uniform array of irregularities” and the degree of nonuniformity allowable within the scope of the claims. As noted by Appellants, the Gubbi Declaration was not submitted to prove definiteness (Request for Rehearing 5, n. 1). Rather, the Appellants provided the Gubbi Declaration to compare “a titanium dental implant [that] was given a treatment according to the method described in this patent application to produce an Osseotite® surface” with “titanium implants [that] were exposed to the two-step procedure described in … Haruyuki.” (Gubbi Decl., ¶D). Dr. Gubbi concluded, “the treatments of [Haruyuki] produced surfaces that do not resemble the surface achieved by the methodology of the subject patent application, as shown in Exhibit A” (Gubbi Decl. ¶ H). As such, the Gubbi Declaration provides the declarant’s observations as to the visual appearance of the prior art surface as compared to the Osseotite® surface, but it is of no assistance in further defining the claim language so as to

distinguish the claimed surface from the prior art surface. In particular, the declaration fails to reach a conclusion that the prior art sample surfaces do not contain “substantially uniform arrays of irregularities.” Rather, Dr. Gubbi merely concludes that the prior art surfaces “do not resemble” the Osseotite® surface (Gubbi Decl., ¶H). Thus, the Appellants do not provide any expert testimony as to what one having ordinary skill in the art would understand a “substantially uniform array of irregularities” to mean in the dental implant art.

In *Seattle Box*, the Federal Circuit confronted an indefiniteness challenge to a patent claim that used the phrase “substantially equal to,” and noted that words of degree can be indefinite if the patent’s specification fails to provide a standard for measuring the degree claimed:

Definiteness problems often arise when words of degree are used in a claim. That some claim language may not be precise, however, does not automatically render a claim invalid. When a word of degree is used the [factfinder] must determine whether the patent's specification provides some standard for measuring that degree. The [factfinder] must decide, that is, whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification.

731 F.2d at 826 (affirming the trial court’s determination that an expert would know the limitations of the claims because the specification clearly sets forth a standard for measuring the degree used in the claim language). The patent concerned an invention for packaging oil pipe of various diameters and weights for transport and claimed, specifically, a “spacer block” “of a height substantially

equal to or greater than the thickness of the tier of pipe length.” *Id.* at 820-21. The alleged infringer challenged the patent as indefinite on the theory that a person of ordinary skill in the art could not determine “just how equal ‘substantially equal to’ is.” *Id.* at 826. The court rejected this challenge, concluding that an expert would have known the claim’s limitations because “[t]he specification clearly sets forth, for example, that the divider blocks are intended to absorb the weight of overhead loads.” *Id.* In addition, “even if [the alleged infringer] needed to experiment so as to determine the limits of the … claims, the claims would not be invalid under section 112.” *Id.* Thus, the information provided in the patent regarding the purpose of the invention, along with additional information that could be obtained through experimentation, was sufficient to provide a “standard” for determining the scope of “substantially equal to,” a term of degree. *See id.* Although *Seattle Box* demonstrates that a standard for measuring a term of degree need not be defined with numerical specificity, it stands for the proposition that some standard must exist even if the “standard” may be derived from information in the patent regarding the purpose of the invention – or of the specific aspect of the invention to which the term of degree applies – as well as from experimentation. *See Seattle Box*, 731 F.2d at 820-21, 826.

In this case, however, consideration of the purpose of the invention does not yield the same type of assistance in understanding the standard by which the term of degree at issue, “substantially uniform,” is to be measured. As we explained above in our discussion of *Medrad*, the purpose of the present invention, as explained by the claims and Specification, is to facilitate osseointegration with the

bone. This information does not provide a standard for measuring the degree of substantially uniformity of the irregularities because a roughened surface with widely varying degrees of irregularities might also facilitate osseointegration. Nor would experimentation help in determining the degree of uniformity of an array of irregularities for facilitating osseointegration, because the Specification does not even provide a measure of the enhancement of integration of the implant to the bone as compared to prior art implants.

Appellants correctly point out that there is no doctrinal rule that requires an applicant to define “substantially” with mathematical precision. *See Modine Mfg. Co. v. United States Int'l. Trade Comm'n.*, 75 F.3d 1545, 1557 (Fed. Cir. 1996), abrogated on other grounds, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558 (Fed. Cir. 2000) (en banc). We further understand that the Patent Office is to give claims “their broadest reasonable interpretation consistent with the specification” and “in light of the specification as it would be interpreted by one of ordinary skill in the art.” *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). However, in this case, we have no evidence in the record as to how the claims would be interpreted by one of ordinary skill in the art. We further note that during prosecution, it is the appellants’ burden to precisely define the invention, not the PTO’s. *In re Morris*, 127 F.3d 1048, 1056 (Fed. Cir. 1997). Appellants always have the opportunity to amend the claims during prosecution. In contrast, during an infringement litigation, such as in those cases relied upon in Appellants’ Request for Rehearing, the claim is construed post-issuance and the patent has a presumption of validity. In such cases, it is the

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challenger's burden to overcome the presumption of validity with evidence clearly showing the claims are indefinite.

In this case, the Specification fails to provide a standard against which one could interpret the claimed degree of uniformity, nor do we see how one would be able to determine the claim scope by experimentation. Further, the Appellants have provided no evidence as to how the claimed "substantially uniform array of irregularities" would be understood by one having ordinary skill in the dental implant art. Therefore, one of ordinary skill would not know what degree of roughness would fall within the claim scope and what would not.

#### DECISION

Accordingly, while we have granted Appellants' request for rehearing to the extent that we have reconsidered our decision, the request is denied with respect to making any changes in the decision. No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2006).

DENIED

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